

Amdt. dated July 15, 2005
Preliminary Amendment

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Original): A method for treating benign prostatic hypertrophy (BPH) comprising administering a therapeutically effective amount of an energolytic agent (EA) to a human subject in need of such treatment, wherein the energolytic agent is an agent that interferes with energy metabolism in prostate epithelial cells.

Claims 2 - 3 are cancelled.

4. (Original): A method for prophylaxis of BPH comprising administering a prophylactically effective amount of an energolytic agent (EA) to a human subject, wherein the energolytic agent is an agent that interferes with energy metabolism in prostate epithelial cells.

5. (Currently amended): The method of claim 1 ~~any of claims 1 to 4~~ wherein the energolytic agent is selected from the group consisting of 2-deoxyglucose, 3-bromopyruvate, gossypol, oxamate, iodoacetate, and apoptolidin, ~~and~~ ~~londamine~~.

Claim 6 is cancelled.

7. (Currently amended): The method of claim 1 ~~any of claims 1 to 6~~ wherein the subject is neither diagnosed with nor under treatment for cancer.

Claim 8 is cancelled.

9. (Currently amended): The method of claim 1 ~~8~~ wherein the subject has a serum PSA less than about 10 ng/ml.

Claim 10 is cancelled.

11. (Currently amended): The method of claim 1 ~~any of claims 1 to 9~~ wherein said energolytic agent is administered in combination with an other treatment for BPH.

Claim 12 is cancelled.

13. (Currently amended): The method of claim 1 ~~any of claims 1 to 12~~, wherein the energolytic agent is administered at least once daily for at least five days.

14. (Currently amended): The method of claim 1 ~~any of claims 1 to 13~~ wherein, when compared to a baseline prior to the initiation of treatment, the subject's:

a) AUASI or IPSS score is decreased by at least 3 points, optionally by at least about 5 points;

b) prostate size has decreased by at least about 20%, optionally at least about 40%; and/or

c) serum PSA levels have decreased by at least about 20%, optionally at least about 40%,

when determined on or after 60 days after the initiation of treatment.

15. (Currently amended): A method for treating BPH comprising (a) diagnosing BPH in a patient, (b) administering an energolytic agent ~~EA~~ to the patient and (c) determining whether one or more manifestations of BPH are reduced in said patient.

16. (Original): A method for treating BPH comprising (a) administering an energolytic agent to a patient diagnosed with BPH and (b) determining whether one or more manifestations of BPH are reduced in said patient.

Claims 17 - 20 are cancelled.

21. (Original): A method for determining the usefulness of a compound for treatment of BPH comprising

- a) contacting a citrate-producing cell with the compound
- b) contacting a citrate-oxidizing cell with the compound
- c) detecting a differential effect of said contacting on said citrate-producing cell

compared to said citrate-oxidizing cell, wherein a differential effect indicates that the agent may be useful for treatment of BPH.

22. (Original): The method of claim 21 wherein the cells are derived from prostate.

23. (Original): The method of claim 22 wherein the cells are human.

24. (Original): The method of claim 22 wherein the citrate-producing cells and citrate-oxidizing cells are cells cultured under hypoxic conditions.

25. (Original): The method of claim 21 wherein the differential effect is induction of apoptosis that is greater in citrate-producing cells compared to citrate-oxidizing cells.

26. (Original): The method of claim 21 wherein the citrate-producing cells are a primary culture of human prostate epithelial cells and the citrate-oxidizing cells are a primary culture of human prostate stromal cells

27. (Original): The method of claim 21 wherein the citrate-producing cells and citrate-oxidizing cells are established cell lines.

28. (Original): The method of claim 21 wherein the citrate-producing cells are LNCaP cells and the citrate-oxidizing cells are PC-3 cells.

29. (Currently amended): A method for determining the usefulness of a compound for treatment of BPH comprising

(a) contacting a citrate-producing cell cultured under conditions of hypoxia with the compound; and

(b) identifying a compound as useful for treatment of BPH if the contacting results in a dose-dependent reduction in ~~HIF-1 α~~ HIF-1alpha expression (measured in the nuclear fraction) of at least about 2-fold.

30. (Original): The method of claim 29 wherein the citrate-producing cell is an LNCaP